UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,210	03/17/2005	Stephen R. Smith	3323	9149

21834 7590 10/28/2008

BECK AND TYSVER P.L.L.C.
2900 THOMAS AVENUE SOUTH
SUITE 100
MINNEAPOLIS, MN 55416

EXAMINER	
GOUGH, TIFFANY MAUREEN	
ART UNIT	**PAPER NUMBER**
1657	
MAIL DATE	**DELIVERY MODE**
10/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/528,210
Filing Date: March 17, 2005
Appellant(s): SMITH ET AL.

Stephanie J. James
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 07/25/2008 appealing from the Office action mailed 11/29/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Unilever PLC (EP 0466244 A1, 1992)

Medipharm (EP 0955061 A1, 1999)

Ibrahim, H.R. (Natural Food Antimicrobial Systems, ed. L S. Naidu, pp. 211-226, New York CRC Press, Inc., 2000)

Nippon (JP 62145025,1987)

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 49-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unilever PLC (EP 0466244 A1, 1992) in view of Medipharm (EP 0955061 A1,1999), Ibrahim (Natural food antimicrobial system, 2000) and Nippon (JP 62145025, 1987).

Appellant claims an antimicrobial composition used as an agent to suppress the growth of enteric pathogens such as *Clostridium perfringens, Escherichia coli, Salmonella typhimurium and Salmonella mbandaka*, either in powdered or aqueous solution or water-soluble form comprising a cell wall lysing substance or salt such as lysozyme, dried egg powder or albumen and a sequestering agent such as an organic acid or a metal chelator which is administered to feedstock as a feed additive to prevent and treat gastrointestinal infections such as necrotic enteritis and diarrheal disease in livestock. Appellant claims the composition ratio of such composition being 2:5:3 by weight. Further appellant claims the use of dried egg powder in such composition is capable of suppressing microbes such as molds and viruses and also enzymes like proteases and lipases in livestock gut. Further, appellant claims cell wall lysing

substance or salt, dried egg powder or albumen, a sequestering agent and a lantibiotic such as nisin, whose ratio in composition is 50:150:50:20.

Unilever PLC (EP 0466244 A1, 1992) disclose a mixture of the cell wall lysing substance lysozyme, antibacterial/lantibiotic nisin and the sequestering agent citric acid or another food-grade adjuvant, effectively preventing the growth of *Listeria monocytogenes* and also other microorganisms such as lactic acid bacteria which is used in connection with suppression of microorganisms in production, packaging and storage of food products, animal feeds, cosmetics and pharmaceutical products (see abstract). They disclose the effectiveness of using lysozyme in combination with citric acid or EDTA and other chelators or an antimycotic such as Pimaricine™ in foods to inhibit *Listeria monocytogenes*, bacteria and yeasts (see pg. 2 "Use of lysozyme" section). Unilever discloses a strong synergism existing between the action of lysozyme, nisin and citric acid (EDTA or salts thereof can be substituted for citric acid). These three ingredients used together effectively prevent the growth of many strains of bacteria and are much more effective when used in combination than when used alone (see pg. 3 "Brief summary of invention and detailed description" paragraphs). They also suggest that antimycotics such a Pimaricine™ , which suppress the growth of molds and yeasts, can be used in combination with such mixture and further suggest that at least one antibacterial compound must be present in the synergistic composition (pg. 4 lines 20-24). Thus Unilever's invention is a composition, which has improved antibacterial properties, comprising a mixture of at least one representative of each group (a) a cell wall lysing substance (b) an antibacterial compound and (c) and adjuvant such as an

organic acid or sequestering agent and further claims the following ratio of such composition (a) 5-2000 mg : (b) 5 x 10^3 -5 x 10^6 IU : (c) 0.5-100 g.

Unilever differs from the claims in that their composition is not disclosed as containing egg powder or albumen and further to suppress the growth of enteric pathogens, specifically *Clostridium sp. , E.coli* and *Salmonella sp.* However, Medipharm (EP 0955061 A1, 1999) discloses an oral product for the prevention and therapy of porcine gastroenteric infections, more specifically directed towards the rotavirus, coronaviruses and enteropathogenic and enterotoxigenic bacterial strains of *Clostridium sp., E.coli* and *Salmonella sp.* The oral compositions raw material is liquid eggs, which are freeze-dried resulting in a powder form product, from which antibodies are obtained. The product exists in a paste, water-soluble powder formula which may be mixed with water, and a powder formula (see pg. 3 “Principle of invention” section).

Further support of the why one would use egg or albumin in an antimicrobial composition is provided by Ibrahim (Natural food antimicrobial system, 2000). Ibrahim discloses that an avian egg is one of many natural antimicrobial systems available. Egg whites also known as albumin, is the egg’s second line of defense against bacteria after the shell and membranes. The proteins in egg whites are thought to prevent invasion of microorganisms into the yolk and most possess antimicrobial properties which hinder the growth and spread of microorganisms. Such antimicrobial properties include lysozyme, which hydrolyzes the peptidoglycan of bacterial cell walls, ovotransferrin, which chelates metal ions, vitamin binding proteins and proteinase inhibitors (see introduction). Even further support is Nippon (JP 62145025, 1987) disclosing an antiviral

agent containing albumen as an active component for the suppression of viruses such as rotavirus (see abstract).

One of ordinary skill in the art would therefore have been motivated by Ibrahim's disclosure of the antimicrobial properties eggs possess and to apply this knowledge to the composition in Medipharms application used for the prevention and therapy of porcine gastroenteric infections, more specifically directed towards the rotavirus, coronaviruses and enteropathogenic and enterotoxigenic bacterial strains of *Clostridium sp. , E.coli* and *Salmonella sp.* and to further apply these advantages to the composition disclosed by Unilever containing a mixture of the cell wall lysing substance lysozyme, antibacterial/lantibiotic nisin and the sequestering agent citric acid or another food-grade adjuvant, effectively preventing the growth of *Listeria monocytogenes* and also other microorganisms such as lactic acid bacteria which is used in connection with suppression of microorganisms in production, packaging and storage of food products, animal feeds, cosmetics and pharmaceutical products.

With respect to the composition ratios in claims 10, 16 and 22, optimizing the ratio as disclosed by Unilever is practiced through routine scientific experimentation. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA

1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."). See MPEP 2144.05

(10) Response to Argument

The brief states that the claimed invention is drawn to a composition taken orally by livestock to combat pathogens within their intestinal system, particularly useful in combating *Clostridium sp., E. coli* and *Salmonella sp.* The brief argues that the Office has relied upon non-analogous art and has used hindsight reasoning in making the rejection of record.

In response to appellant 's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the appellant 's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA

1971). In this case, the products all have an antimicrobial property, so the references are combined because the disclosed products all have the same property.

The brief argues that the Unilever reference (EP0466244 A1) discloses an antimicrobial composition which may be used in animal feedstuffs. The brief argues that Unilever does not teach concern in combating microbe growth within the gut of an animal or what would happen to the compound after it is ingested, i.e. whether it would have efficacy on pathogens within the intestinal environment. Unilever does teach an antimicrobial composition comprising a mixture of the cell wall lysing substance lysozyme, antibacterial/lantibiotic nisin and the sequestering agent citric acid or another food-grade adjuvant in an **animal feedstuff**. They disclose the effectiveness of using lysozyme in combination with citric acid or EDTA and other chelators or an antimycotic to inhibit *Listeria monocytogenes*, bacteria and yeasts (see pg. 2 "Use of lysozyme" section). Unilever discloses a strong synergism existing between the action of lysozyme, nisin and citric acid (EDTA or salts thereof can be substituted for citric acid). These three ingredients used together effectively prevent the growth of many strains of bacteria and **are much more effective when used in combination than when used alone** (see pg. 3 "Brief summary of invention and detailed description" paragraphs).They teach the composition and it's compounds to be edible (p.5, lines 44-46). Further, appellant's claim the composition to be a **feed additive** (see claim 62). While Unilever does not teach the use of albumen in an antimicrobial composition, Medipharm was relied upon to overcome the deficiencies of Unilever, which teach an oral product for the prevention and therapy of porcine gastroenteric infections, more

specifically directed towards the rotavirus, coronaviruses and enteropathogenic and enterotoxigenic bacterial strains of *Clostridium sp. , E.coli* and *Salmonella sp.* The oral compositions raw material is liquid eggs, which are freeze-dried resulting in a powder form product, from which antibodies are obtained. They further that the antibodies in egg yolk are resistant to low pH and proteolytic enzymes and remain active in the gastointestinal tract (p. 4, section 0020). Thus the references are analogous because both references are in the art of animal feed modification.

The brief argues the KSR decision. See the recent Board decision *Ex parte Smith*,--USPQ2d--,slip op at 20,(Bd. Pat. App & Interf. June 25, 2007) (citing *KSR*,82 USPQ2d at 1396) (available at http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf) . The brief states that the Court did recognize that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant filed to combine the elements in the way the claimed new invention does." The brief argues that the Examiner has not cited any reason or motivation to combine the references to arrive at the claimed invention. However, as previously stated on the record, the art of record clearly teaches the claimed composition's components, which are effective in treating and preventing gastrointestinal infections caused by enteric pathogens such as those claimed, i.e. *Clostridium sp., Salmonella sp. E. Coli.* Further, the claimed components; EDTA, citric acid, nisin, lysozyme and albumen, of appellant 's compositions are well known for their bacteriostatic/bactericidal effectiveness against both gram positive and gram-negative bacteria. Such pathogens are also well known in the art to be enteric pathogens of the

gut. Thus one of skill in the art would expect success in administering a composition comprising components which are known in the art for their antibacterial properties and effectiveness against enteric pathogens.

The brief extensively argues the intended use of the compositions disclosed in the art and that of appellant's invention. Appellants claimed invention is drawn to a composition, not a method of use. Further, Appellant argues that the prior art of record teaches antimicrobial compositions and their use ex vivo and that the compositions do not suggest using such compositions for veterinary purposes, i.e. to suppress the growth of enteric pathogens in the gut of livestock. The Office does not agree with appellants argument, given that the references of record in combination clearly teach the claimed antimicrobial composition and its components which are known in the art to be used in suppressing the growth of enteric pathogens. However, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Please note that when appellant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112). Appellant states on the record (Appellant s Arguments filed 08/15/2007) that the references may provide justification or expectation of success for adding egg or albumen to a composition

where the antimicrobial activity of the composition occurs *in vivo* (i.e. in the gut of livestock) and targets the growth of enteric pathogens, yet cannot be distorted to provide motivation for the addition for a composition targeting bacterial growth *ex vivo.* Appellants argument is not understood as appellant clearly admits that there is sufficient justification and expectation of success for adding egg or albumen to a composition where the antimicrobial activity of the composition occurs *in vivo* (i.e. in the gut of livestock) and targets the growth of enteric pathogens.

Appellant further provides reasons as to why one skilled in the art would not be brought to combine the references; that one of skill in the art would not assume that the compositions of the prior art would be effective in suppressing enteric pathogens in the gut of livestock, that the bacteria are different and thrive in different environmental conditions, etc. The brief further states that the compositions of the prior art would not have any effectiveness whatsoever against enteric pathogens in the gut of livestock. However, the art of record clearly teaches the claimed composition's components, which are effective in treating and preventing gastrointestinal infections caused by enteric pathogens such as those claimed, i.e. *Clostridium sp., Salmonella sp. E. Coli.* Further, the claimed components; EDTA, citric acid, nisin, lysozyme and albumen, of appellant 's compositions are well known for their bacteriostatic/bactericidal effectiveness against both gram positive and gram-negative bacteria. Such pathogens are also well known in the art to be enteric pathogens of the gut. Thus one of skill in the art would expect success in administering a composition comprising components which

are known in the art for their antibacterial properties and effectiveness against enteric pathogens. Appellant is directed to MPEP 2111.02 and 2112.

2111.02 Weight of Preamble

"[A] claim preamble has the import that the claim as a whole suggests for it." Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995**). "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim."** Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). See also Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951) (A preamble reciting "An abrasive article" was deemed essential to point out the invention defined by claims to an article comprising abrasive grains and a hardened binder and the process of making it. The court stated "it is only by that phrase that it can be known that the subject matter defined by the claims is comprised as an abrasive article. Every union of substances capable inter alia of use as abrasive grains and a binder is not an abrasive article.'" Therefore, the preamble served to further define the structure of the article produced.).

PREAMBLE STATEMENTS LIMITING STRUCTURE

Any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. See, e.g., Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989) (The determination of whether preamble recitations are structural limitations can be resolved only on review of the entirety of the application "to gain an understanding of what the inventors actually invented and intended to encompass by the claim."); Pac-Tec Inc. v. Amerace Corp., 903 F.2d 796, 801, 14 USPQ2d 1871, 1876 (Fed. Cir. 1990) (determining that preamble language that constitutes a structural limitation is actually part of the claimed invention). See also In re Stencel, 828 F.2d 751, 4 USPQ2d 1071 (Fed. Cir. 1987). (The claim at issue was directed to a driver for setting a joint of a threaded collar, however the body of the claim did not directly include the structure of the collar as part of the claimed article. The examiner did not consider the preamble, which did set forth the structure of the collar, as limiting the claim. The court found that the collar structure could not be ignored. While the claim was not directly limited to the collar, the collar structure recited in the preamble did limit the structure of the driver. "[T]he framework – the teachings of the prior art - against which patentability is measured is not all drivers broadly, but drivers suitable for use in combination with this collar, for the claims are so limited." Id. at 1073, 828 F.2d at 754.).

PREAMBLE STATEMENTS RECITING PURPOSE OR INTENDED USE

The claim preamble must be read in the context of the entire claim. **The determination of whether preamble recitations are structural limitations or mere statements of purpose or use "can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim."** Corning Glass Works, 868 F.2d at 1257, 9 USPQ2d at 1966. **If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction.** Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also Rowe v. Dror, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"); Kropa v. Robie, 187 F.2d at 152, 88 USPQ2d at 480-81 (preamble is not a limitation where claim is directed to a product and the preamble merely recites a property inherent in an old product defined by the remainder of the claim); STX LLC. v. Brine, 211 F.3d 588, 591, 54 USPQ2d 1347, 1350 (Fed. Cir. 2000) (holding that the preamble phrase "which provides improved playing and handling characteristics" in a claim drawn to a head for a lacrosse stick was not a claim limitation). During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims,manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. See, e.g., In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963) (The claims were directed to a core member for hair curlers and a process of making a core member for hair curlers. Court held that the intended use of hair curling was of no significance to the structure and process of making.); In re Sinex, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962) (statement of intended use in an apparatus claim did not distinguish over the prior art apparatus). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) (anticipation rejection affirmed based on Board's factual finding that the reference dispenser (a spout disclosed as useful for purposes such as dispensing oil from an oil can) would be capable of dispensing popcorn in the manner set forth in appellant's claim 1 (a dispensing top for dispensing popcorn in a specified manner)) and cases cited therein. See also MPEP § 2112 - § 2112.02.

The brief argues that there were not a finite number of options to modify Unilever. The brief states that, "one equipped with ordinary creativity would have been faced with a large number of potential agents to combat in vivo bacteria, so the selection of egg

would have required an inventive inspiration." While appellants list of antimicrobial agents on the brief pages 10-12 are quite creative and inventive, the references relied upon do contain a finite number of antimicrobial compounds which are disclosed as being useful in suppressing the growth of microorganisms. Unilever clearly teaches a composition comprising lysozme, citric acid or EDTA, nisin and Medipharm, Ibrahim, and Nippon teach a composition comprising dried egg powder and albumin which are known for its antimicrobial properties, especially useful for gastrointestinal infections of livestock.

The brief argues that the art of record does not teach as much as the Examiner ascribes to it. Specifically the brief states that the art does not show the use of lysozyme for combating gastro-intestinal microbes. Claim 49 is drawn to an antimicrobial composition comprising a ***cell wall lysing substance or its salt***. Claim 51 specifically claims this substance to be ***lysozyme***. The art **clearly** teaches a cell wall lysing substance such as lysozyme (see Unilever, abstract, line 1).

The brief argues the synergistic effects which appellants state are shown in Figure 2. After reviewing Figure 2, it is not clear how one of skill in the art could possibly conclude from Figure 2, appellants alleged synergistic effects. Figure 2 has no legend and fails to illustrate that there is an efficacy for inhibiting C. perfringens when using Blend 1, which is not disclosed in appellants brief. It is not clear from the brief if Blend 1 is the dried egg powder and a sequestering agent or lysozyme, dried egg powder and a sequestering agent, given that no disclosure of Blend 1 is explicitly taught in the brief or even more so in Figure 2.

In conclusion, the art of record clearly teaches antimicrobial compositions comprising the claimed components of appellant's invention which are disclosed as having antimicrobial properties to suppress growth of microorganisms. Furthermore, appellants extensive argument of intended use does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Tiffany M Gough/

Examiner, Art Unit 1657

Conferees:

/JON P WEBER/

Supervisory Patent Examiner, Art Unit 1657

/Julie Burke/

QAS TC1600